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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,871	08/29/2003	Horace Winston Hale	HORA.P0101US	9347
23908	7590	04/01/2009	EXAMINER	
RENNER OTTO BOISSELLE & SKLAR, LLP				COMSTOCK, DAVID C
1621 EUCLID AVENUE		ART UNIT		PAPER NUMBER
NINETEENTH FLOOR		3733		
CLEVELAND, OH 44115				
		MAIL DATE		DELIVERY MODE
		04/01/2009		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/651,871	HALE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DAVID COMSTOCK	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 January 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20,41-61 and 63 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-20,41-61,63 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 09 June 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/20/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 January 2009 has been entered.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-6, 8-11, 14-17, 19-20, 41-44, 46-49, 51-55, 57-61 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by the Soboleski et al. (US Patent Publication Number 2002/0151895).

Soboleski et al. disclose a facet implant comprising a superior implant, 150, having an articulating surface and a fixation surface and configured for placement on a

superior articular facet, a inferior implant, 130, having an articulating surface and a fixation surface and configured for placement on an inferior articular facet and for interacting with a translaminar fixation mechanism, wherein the articulating surface of the superior implant and the articulating surface of the inferior implant are configured to interact, and a translaminar fixation mechanism 136 for securing the inferior implant 130 to the inferior articular facet. The superior implant 150 and the inferior implant 130 comprise a surface fixation mechanism in the form of ridges 152 and 132 respectively. Furthermore, Soboleski et al. teach the use of an implant composed of at least one of cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, and Ti/Al/V (see paragraph 0048).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Soboleski et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Regarding claim 63, the language "adapted to secure the inferior implant to the inferior articular facet by traversing a lamina connected to the inferior articular facet" amounts to

a product-by-process limitation. Since the claim is directed to the product and not the process of using the product, the language directed to how the implant is secured (e.g., "by traversing a lamina" etc.) has not been given patentable weight. As such, the claimed product appears to be substantially the same as that disclosed by Sobeleski et al., since there is therein a means for securing the implant to the facet (e.g., the geometry of the device or the hook configuration). Therefore the burden is upon the applicant to present evidence establishing a nonobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soboleski et al. (US Patent Publication Number 2002/0151895).

Soboleski et al. disclose the claimed invention except for the inferior implant being configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees offset and the superior and inferior implants ranging from about 2 mm thick to about 15 mm thick. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Soboleski et al. with the inferior

implant being configured to interact with the translaminar fixation mechanism such that the translaminar fixation mechanism ranges from about 0 degrees to about 15 degrees offset and the superior and inferior implants ranging from about 2 mm thick to about 15 mm thick, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Soboleski et al. teach that the implants can be of various shapes and sizes (see paragraphs 0045-0047).

Claims 7, 18, 45, 50 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soboleski et al. (US Patent Publication Number 2002/0151895) in view of Yuan et al. (US Patent Publication Number 2005/0143818).

Soboleski et al. disclose the claimed invention except for the fixation surfaces having a porous coating. Yuan et al. disclose a facet implant and teach a fixation surface having a porous coating in order to promote bone ingrowth and fixation (see paragraph 0096). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Soboleski et al. with the fixation surfaces having a porous coating, in view of Yuan et al., in order to promote bone ingrowth and fixation.

***Response to Arguments***

Applicant's arguments filed 20 January 2009, regarding the amended claims, have been considered but are not persuasive.

Upon further consideration, the amendment does not yet overcome the outstanding rejection. As noted in the interview of 12 January 2009, and as acknowledged by Applicant in the remarks, it is necessary that the claims be amended in a way that excludes implants with both smooth and rough surfaces. Applicant's claims recite the limitations following the preamble using the open transition "comprising." As such, the art must have at least what is claimed but may also have other structure. The claims require that the implant at least comprise a surface that is generally smooth. The implant of Soboleski et al. comprises a surface that is generally smooth (e.g., the surface surrounding portion 138/158). Examiner acknowledges that the implant also comprises teeth. But there is nonetheless, a generally smooth surface as well. Moreover, it appears that there is no requirement regarding the state of the implant when the surfaces are capable of articulating. Therefore, for example, while assembled and tightened the surfaces can articulate in at least one direction. When the implant is loosened or disassembled, it is at least capable of moving in an opposite, or another, direction. It appears that an amendment excluding any rough surface and requiring the ability for the assembled implant (or, for example, the implant, in use) to be able to articulate in multiple directions would overcome the rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733

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